K051930

AUG 16 2005

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: Medegen Medical Manufacturing Services
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Ontario, CA 91761
CONTACT PERSON: SALVADORE F. PALOMARES, RAC

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Drug Access Spike
Common Name: Accessory to Piston Syringe
Classification Name: Same

Equivalent Devices:

Manufacturer:	ICU Medical	ICU Medical	Baxter Healthcare Corp
Name:	CLAVE Vial Access Spike	One Time Vial Access Spike	Needle*Less Drug Vial Adapter
510(k) #:	K934591	K934561	K894177

Device Description:
The Drug Access Spike is a plastic conduit that is a means to access drug containers. The device is center on top of the stopper of a drug container. The Drug Access Spike is pushed through the rubber stopper and locks into position. A syringe is attached to the Drug Access Spike in order to draw from the drug container. After detaching the syringe, solution/medications are dispensed into a needleless injection site. The use of a Drug Access Spike eliminates the need for a conventional needle.

On multi-dose containers, a needleless injection site is bonded to the Drug Access Spike. This allows the drug container to be accessed multiple times while maintaining a physical barrier to prevent microbial ingress.

The needleless injection port incorporated into some of the configurations of the Drug Access Spike is the NAC™ Needleless Access Connector. The NAC™ Needleless Access Connector was previously cleared under SE-K011193 and SE-K992268.

Intended Use:
The Drug Access Spike is a device used to aspirate solutions/medications from a drug container (drug vial/bag). The Drug Access Spike may incorporate componentry that aid in the prevention of accidental needle sticks.

Biocompatibility:
The materials used to manufacture the Drug Access Spike meet ISO 10993 Biocompatibility Requirements for External Communicating Devices, Indirect Blood Path.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Medegen Medical Manufacturing Services
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K051930
Trade/Device Name: Drug Access Spike
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe Accessory
Regulatory Class: II
Product Code: FMF
Dated: July 30, 2005
Received: August 1, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K951934

Device Name: **Drug Access Spike**

Indications for Use: The Drug Access Spike is a device used to aspirate solutions/medications from a drug container (drug vial/bag). The Drug Access Spike may incorporate componentry that aid in the prevention of accidental needle sticks.

Prescription Use ___X___ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K951930